

Applicants' claims are supported in a number of different passages in the subject application. Only representative passages are cited below. Additional passages could have been listed, but have not been included for the sake of brevity.

# **PATENT CLAIM 19 AND APPLICANTS' CLAIM 2**

Claim 19 of the '304 Patent is directed to a recombinant expression construct capable of controlling the expression of a lysozyme protein through a promoter in plants.

Applicants' claim 2 corresponds to claim 19 of the '304 Patent and is copied in modified form from the patent. Claim 2 is supported in Applicants' specification as follows:

## **Patent Claim 19**

19. A recombinant expression construct

comprising a nucleotide sequence

## **Applicants' Disclosure**

Constructs were subcloned into the viral vector TTODA, a chimera between tobacco and tomato mosaic viruses.

(p. 47, lines 7-8)

The resultant vector designated SBS5-rGAL-12R, see Figure 2., exhibited stability upon passage on *N. benthamiana* plants.

(p.51, lines 5-6)

We combined a dual promoter from Cauliflower Mosaic Virus (35S), a translational enhancer from Tobacco Etch Virus and a polyadenylation region from the nopaline synthetase gene of *Agrobacterium tumefaciens* with the native human GCB cDNA to create plasmid pBSG638.

(p.22, lines 4-6)

Using a standard *Agrobacterium*-mediated transformation method, we regenerated 93 independent kanamycin-resistant transformants from leaf discs of four different tobacco cultivars.

(p.22, lines 16-18)

(p.49, lines 5-15)

(p. 47, lines 7-8)

We fused the Gal-A cDNA to a plant signal peptide sequence derived from rice alpha-amylase gene.

(p.47, lines 3-4)

The  $\alpha$ -galactosidase gene fragment present in vector rGAL-12R was placed into TMV vector SBS5

The following example describes the series of  $\alpha$ -galactosidase vectors that were

constructed and used.

production. Initially, the human  $\alpha$ -galactosidase A cDNA was fused to a plant signal peptide sequence derived from a rice  $\alpha$ -alpha amylase gene. This chimeric gene was subcloned into the TMV based expression vector TTODA resulting in a construct designated rGAL-A, see Table 1. Vector rGAL-A was modified by the addition of the putative ER retention signal SEKDEL, resulting in the vector designated rGAL-AR, see Table 1. (p.49, lines 5-15).

and a promoter that regulates the expression of the nucleotide sequence

(p.49, lines 5-15)  
(p 22, lines 4-6)

in a plant cell.

(p 22, lines 4-6)  
(p 50, lines 12-14)  
(p 42, lines 1-4)  
(p.30, lines 13-14)  
Transcripts were prepared in vitro and inoculated onto lower leaves of actively growing *Nicotiana benthamiana* plants. (p.51, lines 9-10)  
Young actively growing *Nicotiana benthamiana* plants were inoculated with infectious transcripts of a recombinant plant viral construct containing the lysosomal enzyme transcripts of a recombinant plant viral construct containing the lysosomal enzyme alpha galactosidase gene. (p.44, lines 4-6).

### PROPOSED COUNTS

The following count is proposed for purposes of declaring an interference:

#### PROPOSED COUNT 1

1. **A recombinant expression construct comprising a nucleotide sequence encoding a protein of interest and a promoter that regulates the expression of the nucleotide sequence in a plant cell.**

Proposed Count 1 corresponds to claim 19 of the '304 Patent. Claim 19 recites a

recombinant expression construct comprising a nucleotide sequence encoding a protein of interest and a promoter that regulates the expression of the nucleotide sequence in a plant cell. Thus, claim 19 of the '304 Patent encompasses all of the subject matter of claims 20-39. Claims 37-39 are merely dependent claims and do not add any new subject matter to claim 19.

#### The Remaining Independent Claims

The remaining independent claims in the '304 Patent are claims 1-40, 55, 56, 57 and 59. Claim 1 of the '304 Patent is not patentably distinct from patent claim 19 (Proposed Count 1), as the former merely recites a method for expressing a lysosomal enzyme using the construct defined in claim 19 (Proposed Count 1) in a transgenic plant or plant cell. In addition, the term "protein of interest" included in Proposed Count 1 reads on the term "lysosomal enzyme" included in patent claim 1. Claims 2-18 are dependent from claim 1 of the '304 Patent and therefore they are not patentably distinct from claim 19 or Count 1 for the same reasons.

Claim 40 of the '304 Patent and its dependent claims (41-53) are not patentably distinct from patent claim 19 (proposed count 1). Patent claim 40 includes the language of Claim 19 verbatim in describing the recombinant expression construct and refers to a transgenic plant or plant cell.

#### **CLAIMS TO BE DESIGNATED AS CORRESPONDING TO THE COUNTS**

As noted in 37 C.F.R. § 1.606, all claims that "define the same patentable invention as the count shall be designated as corresponding to the count" and "any single patent claim will be presumed...not to contain separate patentable inventions."

#### PROPOSED COUNT 1

Claims 20-36 depend from claim 19 in U.S. Patent No. 5,929,304. Additionally, as explained above, claims 1, 40 and 59 are not patentable over the corresponding generic claim 19 as they merely recite related species of claim 19. Thus, applying the provisions of 37 C.F.R. § 1.606 to these claims, claims 1-18, 20-39, 40-54, and 59-73 in the '304 Patent are directed to the same invention. Accordingly, claims 1-18, 20-39, 40-54 and 59-73 should be designated as corresponding to Proposed Count 1.

Applicants' new claim 2 should also be designated as corresponding to Proposed Count 1, as this claim defines the same invention as claims 1-18, 20-39, 40-54 and 59-73 of the '304 Patent.

Applicants reserve the right to challenge to propriety of the Proposed Count, the designation of any claim as corresponding to a count of the Proposed Count, or the

patentability of any claim during the preliminary motion period in an interference, or otherwise.

**ENTITLEMENT TO EARLIER  
FILING DATE UNDER 35 U.S.C. § 120**

Applicants specification claims the benefit of earlier-filed related applications. Applicants are of the view tha they are entitled to the benefit of their parent applications dating back to February 26, 1988.

**COMPLIANCE WITH 37 C.F.R. § 1.607(a)**

This request for interference complies with the requirements of 37 C.F.R. § 1.607(a):

- (1) The patent is identified as U.S. Patent No. 5,929,304 to Radin et al.;
- (2) At least one proposed count has been presented;
- (3) Claims in the '304 Patent corresponding the Proposed Count:
  - (a) Claims 1-54 and 59-73 in the '304 Patent should be designated as corresponding to Proposed Count 1;
- (4) Applicants' claims corresponding to each Proposed Count:
  - (a) Applicants' claim 2 should be designated as corresponding to Proposed Count 1;
- (5) Applicants' claims 2 has been applied to the subject application.

Applicants respectfully request that an interference be expeditiously declared with U.S. Patent 5,929,304. Applicants further request that they be accorded benefit of the filing U.S. Serial No. 07/170,771, filed February 26, 1988.

A showing under 37 C.F.R. § 1.608(b) is not required, because Applicants' effective filing date of February 26, 1988 antedates the date of September 14, 1995, which is the earliest date that could possibly be accorded to U.S. Patent 5,929,304. Applicants do not concede that the patentees of the '304 Patent are entitled to the filing date earlier than September 14, 1995, the date of their provisional Application No. 60/003,737.

The Commissioner is hereby authorized to charge any fee or underpayment, or credit any overpayment, to the Howrey & Simon Deposit Account No. 08-3038 for any matter in connection with this communication, including any fee for extension of time which may be required.

Respectfully submitted,

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